

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESale PRICE  
LITIGATION

MDL No. 1456  
Master File No.: 01-CV-12257-PBS  
(original S. D. Iowa No. 4:07-cv-00461-  
JAJ-CFB)

THIS DOCUMENT RELATES TO:

Judge Patti B. Saris

*State of Iowa v.  
Abbott Laboratories Inc., et al.*

**ANSWER AND AFFIRMATIVE DEFENSES OF  
ABBOTT LABORATORIES INC. TO THE STATE OF IOWA'S COMPLAINT**

Defendant Abbott Laboratories Inc. ("Abbott"), by and through its attorneys, hereby states its Answer and Affirmative Defenses to the Plaintiff State of Iowa's Complaint, dated October 9, 2007, as follows:

**PRELIMINARY STATEMENT**

Plaintiff's Complaint (the "Complaint") improperly refers to Abbott, other Defendants, and third parties on a collective basis, failing to plead with requisite particularity allegations against Abbott. This is insufficient to apprise Abbott of the allegations asserted against it. Abbott has nevertheless attempted to respond to Plaintiff's allegations to the extent possible.

To the extent the allegations in the Complaint refer to the knowledge, conduct or actions of other persons or entities, Abbott is generally without knowledge or information sufficient to form a belief as to the truth of those allegations. Abbott states that it is answering Plaintiff's allegations solely on behalf of itself, even when Plaintiff's allegations refer to alleged conduct by Abbott and other persons or entities.

The Complaint also contains purported quotations from a number of sources. In answering allegations consisting of quotations, Abbott's failure to deny that the material quoted was contained in a document or was uttered by the person or entity quoted or Abbott's reference to the full document instead of the quote shall not constitute an admission that the substantive content of the quote or document is or is not true or that the material is relevant or admissible in this action.

Abbott denies each and every allegation contained in the Complaint and the exhibits thereto, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos or speculation contained in any particular averment or in the Complaint as a whole. In addition, Abbott specifically denies any allegations contained in headings, footnotes, or unnumbered paragraphs in the Complaint. For ease of reference, Abbott has included in this Answer and Affirmative Defenses certain captions used in the Complaint, but specifically denies any allegations contained in, or inferences that could be drawn from, those captions.

These comments and objections are incorporated, to the extent appropriate, into each unnumbered and numbered paragraph of this Answer.

### **SPECIFIC RESPONSES**

1. Abbott admits that the State of Iowa (the "State") seeks to bring this action as alleged in Paragraph 1 of the Complaint, but Abbott denies that there is any basis for the State to do so and denies that the State is entitled to any relief.

2. To the extent the allegations in Paragraph 2 are directed at Abbott, Abbott denies them. Abbott specifically denies that it “purposefully report[s] false and inflated price information.” To the extent the allegations in Paragraph 2 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

3-4. To the extent the allegations in Paragraphs 3 through 4 are directed at Abbott, Abbott denies them. Abbott specifically denies that it submits “false and inflated pricing information in order to ‘create a spread.’” Abbott further denies the characterization of “spread” in Paragraphs 3 through 4. To the extent the allegations in Paragraphs 3 through 4 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

5. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5.

6. To the extent the allegations in Paragraph 6 are directed at Abbott, Abbott denies them. Abbott specifically denies that it “purposefully manipulate[s] a market that, by defendants’ own design, is extremely complicated and non-transparent.” To the extent the allegations in Paragraph 6 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

7-8. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 7 through 8.

9. To the extent the allegations in Paragraph 9 are directed at Abbott, Abbott denies them. Abbott specifically denies that it engages in any “unlawful price reporting activity [that] infects all four [pricing] benchmarks and renders each of them false and inflated.” To the extent the allegations in Paragraph 9 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

10. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10, except that it admits that it pays Medicaid rebates to Iowa and that such rebates lower the price Iowa Medicaid pays for Abbott’s prescription drugs. To the extent the allegations in Paragraph 10 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

11. To the extent the allegations in Paragraph 11 are directed at Abbott, Abbott denies them. Abbott specifically denies that it does not accurately report Best Prices. To the extent the allegations in Paragraph 11 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

12. To the extent the allegations in Paragraph 12 are directed at Abbott, Abbott denies them. Abbott specifically denies that it engages in “unlawful pricing schemes,” the “manipulation of the Medicaid program” or the “improper reporting of false and inflated pricing information” resulting in “overcharges . . . to the Iowa Medicaid Program.” To the extent the allegations in Paragraph 12 are directed at

parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

13. To the extent the allegations in Paragraph 13 are directed at Abbott, Abbott denies them. Abbott specifically denies that it engages in “wrongful practices” that have a “pernicious . . . effect on the public fisc.” To the extent the allegations in Paragraph 13 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

14-15. Abbott admits that it voluntarily participates in the Iowa Medicaid program, but denies that it has violated any State or Federal law. To the extent the allegations in Paragraphs 14 through 15 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 14 through 15 refer to judicial opinions, those sources speak for themselves, and any characterizations thereof are denied.

16. To the extent the allegations in Paragraph 16 are directed at Abbott, Abbott denies them. Abbott specifically denies that it “intentionally report[s] false prices to the government.” To the extent the allegations in Paragraph 16 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

17. To the extent the allegations in Paragraph 17 are directed at Abbott, Abbott denies them. Abbott specifically denies that it engages in “fraudulent, unfair and deceptive practices.” To the extent the allegations in Paragraph 17 are

directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

18. Abbott admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies any liability to Plaintiff with respect to any such NDCs. To the extent the allegations in Paragraph 18 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

19. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19. To the extent the allegations in Paragraph 19 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

20. To the extent that the allegations in Paragraph 20 are directed at Abbott, Abbott denies them, except Abbott admits that it manufactures and sells prescription drugs and that it participates in the Iowa Medicaid Program. To the extent the allegations in Paragraph 20 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

21. Abbott admits that it conducts business in the State of Iowa. To the extent the allegations in Paragraph 21 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

22. Abbott admits that it is “engaged in the business of manufacturing and selling pharmaceuticals” and that its principal place of business is located in Abbott Park, Illinois. Abbott denies the remaining allegations in Paragraph 22.

23-58. The allegations in Paragraphs 23 through 58 are directed to other defendants and require no response from Abbott. To the extent a response is deemed to be required, Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 23 through 58.

59. Abbott admits that the State seeks to bring this action as alleged in Paragraph 59, but Abbott denies there is any basis for the State to do so and denies that the State is entitled to any relief.

60-61. Paragraphs 60 through 61 state legal conclusions as to which no response is required. To the extent a response is deemed to be required, Abbott denies the allegations in Paragraphs 60 through 61, and notes that this captioned matter has been transferred to this Court by the Judicial Panel on Multi District Litigation, pursuant to 28 U.S.C. § 1407.

62. With respect to the allegations in Paragraph 62, Abbott admits that Medicaid was established by Title XIX of the Social Security Act. Abbott further states that the provisions of Title XIX speak for themselves, and any characterizations thereof are denied.

63. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 63, except Abbott admits that state

participation in Medicaid is voluntary and that state Medicaid plans must be approved by the federal government. To the extent the allegations in Paragraph 63 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

64-65. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 64 through 65. To the extent the allegations in Paragraphs 64 through 65 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

66. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 66, except Abbott admits that national drug codes are assigned to prescription drugs.

67. To the extent the allegations in Paragraph 67 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Abbott otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 67.

68. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68. To the extent the allegations in Paragraph 68 refer to an OIG report, the report speaks for itself, and any characterizations thereof are denied.

69. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69. To the extent the allegations in



Paragraph 69 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

70. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 70.

71-72. To the extent the allegations in Paragraphs 71 through 72 are directed at Abbott, Abbott denies them. Abbott further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 71 through 72 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

73-80. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 73 through 80 or their subsections. To the extent the allegations in Paragraphs 73 through 80 or their subsections refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

81. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 81, except that it admits that pricing compendia such as First DataBank and Medi-Span publish AWP's and FUL's, and denies that Abbott has any control over such prices.

82. To the extent the allegations in Paragraph 82 are directed at Abbott, Abbott denies them. Abbott specifically denies that it “purposefully and fraudulently conceal[s]” the “true prices” of its drugs by “claiming they are proprietary trade secrets.” To the extent the allegations in Paragraph 82 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

83. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 83.

84. To the extent the allegations in Paragraph 84 are directed at Abbott, Abbott denies them. Abbott specifically denies that it “fraudulently misrepresent[s]” its true prices or that it reports “false and inflated prices.” To the extent the allegations in Paragraph 84 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

85. To the extent the allegations in Paragraph 85 are directed at Abbott, Abbott denies them, except that Abbott admits that Exhibit A purports to identify total expenditures by Defendant. Abbott specifically denies any “unfair practices, deception, and fraud.” To the extent the allegations in Paragraph 85 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

86. To the extent the allegations in Paragraph 86 are directed at Abbott, Abbott denies them. Abbott specifically denies conducting any “fraudulent practices.” To the extent the allegations in Paragraph 86 are directed at parties other than

Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

87-89. To the extent the allegations in Paragraphs 87 through 89 are directed at Abbott, Abbott denies them. Abbott specifically denies that it reports “false and inflated” “WACs or WAC equivalents.” To the extent the allegations in Paragraphs 87 through 89 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

90-92. To the extent the allegations in Paragraphs 90 through 92 are directed at Abbott, Abbott denies them. Abbott further states that these allegations wrongly assume that discounts, chargebacks and other price concessions are supposed to be included in prices reported to industry compendia. To the extent the allegations in Paragraphs 90 through 92 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

93-98. To the extent the allegations in Paragraphs 93 through 98 are directed at Abbott, Abbott denies them, except Abbott admits that it has provided certain pricing information for its drugs to various industry pricing compendia and that publishers apply their own markups to the list prices. Abbott specifically denies that it “either report[s] or caused to be reported false and inflated AWP,” “false WAC or WAC equivalents,” or that Abbott “alone control[s] the false and inflated AWP that are published for [its] drugs.” Abbott further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual

average of wholesale prices. To the extent the allegations in Paragraphs 93 through 98 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

99. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 99.

100. To the extent the allegations in Paragraph 100 are directed at Abbott, Abbott denies them. To the extent the allegations in Paragraph 100 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

101. To the extent the allegations in Paragraph 101 or the exhibit referenced therein are directed at Abbott, Abbott denies them. To the extent the allegations in Paragraph 101 or the exhibit referenced therein are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

102-108. To the extent the allegations in Paragraphs 102 through 108 are directed at Abbott, Abbott denies them. To the extent the allegations in Paragraphs 102 through 108 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 102 through 108 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

109. The allegations in Paragraph 109 require no response from Abbott on the grounds that the Iowa SMAC claims have been dismissed by the Court.

110-128. To the extent the allegations in Paragraphs 110 through 128 are directed at Abbott, Abbott denies them, except Abbott admits that it has executed a rebate agreement with HHS. Abbott further states that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to Abbott. In any event, the rebate agreement speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 110 through 128 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 110 through 128 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

129-132. To the extent the allegations in Paragraphs 129 through 132 are directed at Abbott, Abbott denies them, and further states that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to Abbott. To the extent the allegations in Paragraphs 129-132 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 129-132 refer to statutes, regulations or reports, those sources speak for themselves, and any characterizations thereof are denied.

133. To the extent the allegations in Paragraph 133 are directed at Abbott, Abbott denies them. Abbott specifically denies that it has participated in any “pricing scheme . . . by exacerbating the complexities of the . . . drug market.” To the

extent the allegations in Paragraph 133 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

134. To the extent the allegations in Paragraph 134 are directed at Abbott, Abbott denies them. Abbott specifically denies that it “purposefully conceal[s] true prices.” To the extent the allegations in Paragraph 134 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 134 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

135. To the extent the allegations in Paragraph 135 are directed at Abbott, they are denied. To the extent the allegations in Paragraph 135 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

136. To the extent the allegations in Paragraph 136 are directed at Abbott, they are denied, except Abbott admits that certain of its contracts are subject to confidentiality agreements and that Abbott does offer discounts to certain of its customers for certain drugs. To the extent the allegations in Paragraph 136 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

137. To the extent the allegations in Paragraph 137 are directed at Abbott, Abbott denies them. Abbott specifically denies that it “obscure[s] the true prices for [its] drugs with [its] policy of treating different classes of trade differently.” To the

extent the allegations in Paragraph 137 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

138-139. To the extent the allegations in Paragraphs 138 through 139 are directed at Abbott, Abbott denies them. Abbott specifically denies that it “maintain[s] two sets of pricing records: one with [] inflated prices and another with [] actual prices.” To the extent the allegations in Paragraphs 138 through 139 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 138 through 139 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

140-141. To the extent the allegations in Paragraphs 140 through 141 are directed at Abbott, Abbott denies them. Abbott specifically denies that it “hide[s its] real drugs prices by secretly providing free drugs and phony grants” or that it conceals its true prices “to create spreads between actual cost and reimbursement amounts . . . to influence market share.” To the extent the allegations in Paragraphs 140 through 141 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

142. To the extent the allegations in Paragraph 142 are directed at Abbott, Abbott denies them. To the extent the allegations in Paragraph 142 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

143. To the extent the allegations in Paragraph 143 are directed at Abbott, Abbott denies them. Abbott further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraph 143 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

144-145. To the extent the allegations in Paragraphs 144 through 145 are directed at Abbott, Abbott denies them. Abbott specifically denies that it has engaged in any “unlawful and undisclosed manipulation of the price reporting system” or caused the “publication of a false WAC,” AWP, or FUL. To the extent the allegations in Paragraphs 144-145 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

146. To the extent the allegations in Paragraph 146 are directed at Abbott, Abbott denies them. Abbott specifically denies that it has “caus[ed] false prices to be published.” To the extent the allegations in Paragraph 146 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

147. To the extent the allegations in Paragraph 147 are directed at Abbott, Abbott denies them. Abbott specifically denies that it “submit[s] false and inflated wholesale price information in order to create a spread.” Abbott further denies the characterization of “spread” in Paragraph 147. To the extent the allegations in



Paragraph 147 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

148. To the extent the allegations in Paragraph 148 are directed at Abbott, Abbott denies them. Abbott specifically denies that it has “corrupted the market for prescription drugs” or has “deliberately sought to create a powerful financial incentive for providers to prescribe drugs based primarily on the spread.” Abbott further denies the characterization of “spread” in Paragraph 148. To the extent the allegations in Paragraph 148 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

149-150. To the extent the allegations in Paragraphs 149 through 150 are directed at Abbott, Abbott denies them. Abbott specifically denies that it “market[s] its products based on the spread between reimbursement (based on AWP, WAC, or a WAC equivalent) and actual acquisition cost” or that it “compete[s] on reimbursement and profit rather than cost.” To the extent the allegations in Paragraphs 149 through 150 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

151-152. To the extent the allegations in Paragraphs 151 through 152 are directed at Abbott, Abbott denies them. To the extent the allegations in Paragraphs 151 through 152 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 151 through 152 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

153-154. To the extent the allegations in Paragraphs 153 through 154 are directed at Abbott, Abbott denies them. Abbott specifically denies that it has “intentionally manipul[at]ed] the nation’s drug reimbursement system . . . with false and inflated prices.” To the extent the allegations in Paragraphs 153 through 154 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

155-157. To the extent the allegations in Paragraphs 155 through 157 are directed at Abbott, Abbott denies them. Abbott specifically denies that it reports “reimbursement prices . . . to the publishing compendia” or that it engages in “purposeful AWP manipulation.” Abbott further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 155 through 157 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 155 through 157 refer to HHS OIG reports, the reports speak for themselves, and any characterizations thereof are denied.

158. To the extent the allegations in Paragraph 158 are directed at Abbott, Abbott denies them. Abbott specifically denies that it reports “price information that . . . does not comply with the HHS OIG’s guidelines” by not accounting for various types of discounts. To the extent the allegations in Paragraph 158 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

159-165. Abbott denies knowledge or information to form a belief as to the truth of the allegations in Paragraphs 159 through 165, except Abbott admits that it participates in the Federal Medicaid Rebate Program through which Iowa Medicaid is obligated to reimburse providers for Abbott drugs. Abbott further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices or have an expected relationship to such an average. To the extent the allegations in Paragraphs 159 through 165 refer to judicial opinions, those sources speak for themselves, and any characterizations thereof are denied.

166. To the extent the allegations in Paragraph 166 are directed at Abbott, Abbott denies them. To the extent the allegations in Paragraph 166 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

167-171. To the extent that the allegations in Paragraphs 167 through 171 are directed at Abbott, Abbott denies them, except Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegation that the “Iowa Medicaid Program spent over \$1.6 billion for defendants’ drugs between 1992 and 2005 alone.” Abbott specifically denies that it “knowingly interfered with Iowa’s ability to reimburse providers at EAC.” To the extent the allegations in Paragraphs 167 through 171 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

172-177. With respect to the allegations in Paragraphs 172 through 177, Abbott admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies the accuracy of the data listed therein. To the extent the remaining allegations in Paragraphs 172 through 177 or Exhibit B are directed at Abbott, Abbott denies them. Abbott specifically denies that it “routinely submitted false prices” to pricing compendia. Abbott further denies the characterization of “spread” in Paragraphs 172 through 177 and Exhibit B. To the extent the allegations in Paragraphs 172 through 177 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

178. To the extent the allegations in Paragraph 178 are directed at Abbott, Abbott denies them. To the extent the allegations in Paragraph 178 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

179. To the extent the allegations in Paragraph 179 are directed at Abbott, Abbott denies them, except Abbott admits that its contracts with certain purchasers sometimes included discounts. To the extent the allegations in Paragraph 179 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

180. To the extent the allegations in Paragraph 180 or the exhibit referenced therein are directed at Abbott, Abbott denies them. To the extent the allegations in Paragraph 180 or the exhibit referenced therein are directed at parties other

than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

181. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 181 or the exhibit referenced therein, except Abbott denies that it engaged in any “fraud.”

182. Abbott denies the allegations in Paragraph 182 and the exhibit referenced therein.

183-187. Abbott denies the allegations in Paragraph 183 through 187.

188. Abbott denies the allegations in Paragraph 188. To the extent the allegations in Paragraph 188 refer to an HHS report, the report speaks for itself, and Abbott denies any characterization or inference resulting from the Plaintiff’s citation to the HHS report. Abbott denies that Plaintiff has accurately characterized the findings, opinions, statements, or conclusions of the HHS report.

189. Abbott denies the allegations in Paragraph 189. To the extent that the allegations in Paragraph 189 refer to a letter from Representative Stark, the letter speaks for itself, and Abbott denies any characterization or inference resulting from the Plaintiff’s citation. Abbott denies that Plaintiff’s have accurately characterized the findings, opinions, statements, or conclusions of the letter.

190. Abbott denies allegations in Paragraph 190.

191. Abbott denies the allegations in Paragraph 191. To the extent that the allegations in Paragraph 191 refer to a document, the document speaks for itself, and Abbott denies any characterization or inference resulting from the Plaintiff's citation. Abbott denies that Plaintiff's have accurately characterized the findings, opinions, statements, or conclusions of the document.

192-193. Abbott denies the allegations in Paragraphs 192 through 193.

194. Abbott denies that it has engaged in any "wrongful conduct" or in a "routine practice of reporting false and inflated wholesale pricing information and non-compliance with rebate obligations." As for the remainder of the allegations in Paragraph 194, Abbott denies knowledge or information sufficient to form a belief as to their truth.

195. Abbott denies the allegations in Paragraph 195, except Abbott admits that it has been named as a defendant in lawsuits filed by the Department of Justice and by the States of Alabama, Alaska, California, Hawaii, Illinois, Idaho, Kentucky, Mississippi, Montana, Nevada, Pennsylvania, South Carolina, Texas, West Virginia, and Wisconsin and by the City of New York and 42 New York Counties. Abbott specifically denies that there is any basis for those lawsuits.

196. Abbott denies the Plaintiff's characterization or inference of Abbott's settlement agreement regarding its Ross Products Division in 2003. Abbott admits that it paid \$622 million as a result of that settlement agreement. Abbott denies any remaining allegations in Paragraph 196.

197. Abbott admits that it has had a joint marketing agreement with MedImmune. Abbott denies any remaining allegations in Paragraph 197.

198. Abbott admits that, along with Takeda Pharmaceutical Company Limited, it owned shares in TAP Pharmaceutical Products Inc., but denies that plaintiff has accurately characterized TAP's 2001 settlement related to the drug Lupron and therefore denies the remaining allegations of Paragraph 198.

199. With respect to the allegations in Paragraph 199, Abbott denies knowledge or information sufficient to form a belief as to their truth.

200. Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegation that "Abbott also is the subject of the investigation led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is improperly using the nominal price exception to the Best Price reporting requirement." Abbott denies the remaining allegations in Paragraph 200.

201-613. The allegations in Paragraphs 201 through 613 are directed to other Defendants and require no response from Abbott. To the extent a response is deemed to be required, Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 201 through 613.

614-616. To the extent the allegations in Paragraphs 614 through 616 are directed at Abbott, Abbott denies them, except Abbott denies knowledge or information sufficient to form a belief as to the truth of the allegation that Iowa's Medicaid program "spent over \$1.6 billion for defendants' drugs in state and federal dollars from 1992

through 2005 alone.” Abbott specifically denies that it was involved in any “false price reporting scheme” or “misconduct,” or that it has been “unjustly enriched.” To the extent the allegations in Paragraphs 614 through 616 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

617-632. To the extent the allegations in Paragraphs 617 through 632 are directed at Abbott, Abbott denies them. Abbott further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 617 through 632 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 630 refer to *The Pink Sheet*, that document speaks for itself, and any characterizations thereof are denied.

## **COUNT I**

### **VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. 1396r-8 (FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)**

633. In response to Paragraph 633, Abbott repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 632.

634-642. To the extent the allegations in Paragraphs 634 through 642 are directed at Abbott, Abbott states that the Court has dismissed the claim to which these allegations relate. To the extent that a response is still required, Abbott denies the allegations as to itself. To the extent the allegations in Paragraphs 634 through 642 are



directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

## **COUNT II**

### **BREACH OF CONTRACT**

643. In response to Paragraph 643, Abbott repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 642.

644-651. To the extent the allegations in Paragraphs 644-651 are directed at Abbott, Abbott states that the Court has dismissed the claim to which these allegations relate. To the extent that a response is still required, Abbott denies the allegations as to itself. To the extent the allegations in Paragraphs 644-651 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth.

## **COUNT III**

### **IOWA CONSUMER FRAUD ACT (Iowa Code § 714.16)**

652. In response to Paragraph 652, Abbott repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 651.

653. To the extent the allegations in Paragraph 653 and the exhibits referenced therein are directed at Abbott, Abbott denies them. To the extent the allegations in Paragraph 653 are directed at parties other than Abbott, Abbott denies

knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 653 refers to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

654-657. To the extent the allegations in Paragraphs 654 through 657 and the sub-parts thereto are directed at Abbott, Abbott denies them. To the extent the allegations in Paragraphs 654 through 657 and the sub-parts thereto are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 654 through 657 and the sub-parts thereto refer to statutes, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 654 through 657 and the sub-parts thereto contain legal conclusions, no response is required.

#### **COUNT IV**

##### **FRAUD**

658. In response to Paragraph 658, Abbott repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 657.

659-662. To the extent the allegations in Paragraphs 659 through 662 and the exhibits referenced therein are directed at Abbott, Abbott denies them. To the extent the allegations in Paragraphs 659 through 662 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 659 through 662 refer to Iowa law, those sources speak for themselves, and any characterizations thereof are denied. To the extent the

allegations in Paragraphs 659 through 662 contain legal conclusions, no response is required.

**COUNT VIII**  
**UNJUST ENRICHMENT**

663. In response to Paragraph 663, Abbott repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 662.

664-666. To the extent the allegations in Paragraphs 664 through 666 are directed at Abbott, Abbott denies them. To the extent the allegations in Paragraphs 664 through 666 are directed at parties other than Abbott, Abbott denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 664 through 666 contain legal conclusions, no response is required.

667-675. Abbott denies that the State is entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph and Paragraphs 667 through 675 of the Complaint.

**AFFIRMATIVE DEFENSES**

Abbott reasserts and incorporates herein by reference the assertions of paragraphs 1 through 675 hereof.

**First Affirmative Defense**

Plaintiff fails to state a claim against Abbott upon which relief may be granted.

**Second Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because it did not rely on any alleged misrepresentations or fraud by Abbott. Plaintiff knew that providers could obtain Abbott drugs at prices below AWP prior to the relevant time period stated in the Complaint.

**Third Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

**Fourth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the filed rate doctrine.

**Fifth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the state action doctrine.

**Sixth Affirmative Defense**

To the extent Plaintiff obtains recovery in any other case predicated on the same factual allegations, Plaintiff is barred from seeking recovery against Abbott based on the Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

**Seventh Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Abbott in judicial, legislative, or administrative proceedings of any kind or at any level of government.

**Eighth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff has released, settled, entered into an accord and satisfaction or otherwise compromised Plaintiff's claims.

**Ninth Affirmative Defense**

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, the Federal Medicaid Act, and the Prescription Drug, Improvement and Modernization Act of 2003, including all amendments to the same and all regulations promulgated thereunder.

**Tenth Affirmative Defense**

Plaintiff's claims against Abbott are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

**Eleventh Affirmative Defense**

Plaintiff fails to state with particularity facts to support claims of fraudulent conduct, fraudulent concealment and the multi-source allegations against Abbott contained in the Complaint.

**Twelfth Affirmative Defense**

Any and all actions taken by Abbott with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

**Thirteenth Affirmative Defense**

Abbott's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiff.

**Fourteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a consumer within the meaning of the Iowa Consumer Fraud Act.

**Fifteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a person within the meaning of the Iowa Consumer Fraud Act.

**Sixteenth Affirmative Defense**

Some or all of Plaintiff's claims against Abbott arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

**Seventeenth Affirmative Defense**

Abbott denies that Plaintiff has a valid consumer protection claim against Abbott under the Iowa Consumer Fraud Act. However, if such claim is found to exist, Abbott pleads all available defenses under the Act.

**Eighteenth Affirmative Defense**

To the extent that Plaintiff attempts to seek equitable relief against Abbott, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

**Nineteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

**Twentieth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by Abbott after the filing of the Complaint.

**Twenty-First Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because the damages alleged are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

**Twenty-Second Affirmative Defense**

Plaintiff's claims against Abbott are barred, in whole or in part, due to their failure to join indispensable parties.

**Twenty-Third Affirmative Defense**

Plaintiff's claims against Abbott are barred, in whole or in part, because Plaintiff has not suffered damages as a result of the matters alleged in the Complaint.

**Twenty-Fourth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, (1) because Plaintiff failed to mitigate damages, and that failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Abbott; (2) because Plaintiff would be unjustly enriched if allowed to recover any portion

of the damages alleged in the Complaint; and (3) because damages are speculative and remote and because of the impossibility of ascertaining and allocating alleged damages.

**Twenty-Fifth Affirmative Defense**

Abbott is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

**Twenty-Sixth Affirmative Defense**

Plaintiff's claims against Abbott are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Iowa Constitution.

**Twenty-Seventh Affirmative Defense**

Plaintiff's claims against Abbott are preempted by the Commerce Clause and/or the dormant Commerce Clause of the United States Constitution.

**Twenty-Eighth Affirmative Defense**

Plaintiff's claims against Abbott are barred, in whole or in part, because they violate Abbott's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Iowa Constitution, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

**Twenty-Ninth Affirmative Defense**

Plaintiff's claims against Abbott are barred because Plaintiff and/or its agents knew and were aware that AWP was not an actual average of wholesale prices or the actual acquisition cost of pharmaceuticals. Legal and equitable principles preclude this action for damages and injunctive relief.



**Thirtieth Affirmative Defense**

The claims alleged herein, based on the facts alleged, are barred in whole or in part by Plaintiff's own negligence or gross negligence and the doctrines of comparative and/or contributory negligence. Among other things, the claims disregard Iowa's obligations under federal law.

**Thirty-First Affirmative Defense**

Plaintiff's prayers for relief in the form of restitution are barred, in whole or in part, because Abbott did not retain any money belonging to Plaintiff as a result of any alleged overpayments.

**Thirty-Second Affirmative Defense**

Plaintiff has failed to plead with particularity allegations of fraud by Abbott contained in the Complaint.

**Thirty-Third Affirmative Defense**

Plaintiff's claims for fraud and fraudulent concealment are barred because the Plaintiff cannot predicate a claim for fraud on reliance by a third party.

**Thirty-Fourth Affirmative Defense**

Plaintiff's claims against Abbott are barred because Plaintiff lacks standing or capacity to bring the some or all of the claims asserted against Abbott under Iowa law.

**Thirty-Fifth Affirmative Defense**

Plaintiff's claims against Abbott are barred in whole or in part by the doctrine of voluntary payment.

**Thirty-Sixth Affirmative Defense**

Plaintiff's claims against Abbott for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

**Thirty-Seventh Affirmative Defense**

Plaintiff's claims against Abbott for unjust enrichment are barred because the Complaint does not allege that Defendants received any payment or property from the Plaintiff.

**Thirty-Eighth Affirmative Defense**

Plaintiff's claims against Abbott for injunctive relief against Abbott are barred by the doctrines of *in pari delicto* and/or unclean hands.

**Thirty-Ninth Affirmative Defense**

Plaintiff's claims against Abbott are misjoined with Plaintiff's claims against other Defendants and must be severed.

**Fortieth Affirmative Defense**

Any damages recovered by the Plaintiff must be limited by any applicable statutory ceiling on recoverable damages.

**Forty-First Affirmative Defense**

To the extent punitive damages are sought, Plaintiff's punitive damages claims against Abbott (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against Abbott; (3) cannot be sustained because the laws regarding the standards for determining liability for, and the amount of, punitive damages fail to give Abbott prior notice of the conduct for which punitive damages may be imposed and the severity

of the penalty that may be imposed and are void for vagueness in violation of Abbott's due process rights guaranteed by the Fifth and the Fourteenth Amendments to the United States Constitution; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Abbott's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and be improper under the Iowa Constitution and Iowa common law.

**Forty-Second Affirmative Defense**

Plaintiff fails to allege facts or a cause of action against Abbott sufficient to support a claim for prejudgment interest or any other relief.

**Forty-Third Affirmative Defense**

Plaintiff has not suffered, and will not suffer, any injuries to a legally protected or cognizable interest by reason of the conduct of Abbott as alleged in the Complaint.

**Forty-Fourth Affirmative Defense**

Plaintiff's claims against Abbott are barred because Abbott has complied with all applicable regulations of the federal and state governments.

**Forty-Fifth Affirmative Defense**

Plaintiff's claims against Abbott are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of intervening or superseding conduct of third parties.

**Forty-Sixth Affirmative Defense**

Plaintiff's claims against Abbott are barred, in whole or in part, because Abbott did not make any false statements to the Plaintiff. As to any statement asserted against Abbott that Plaintiff alleges to be false or misleading, Abbott had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

**Forty-Seventh Affirmative Defense**

Plaintiff fails to allege facts or a cause of action sufficient to support a claim against Abbott for compensatory damages, attorneys' fees, enhanced damages, treble damages and/or legal fees or costs.

**Forty-Eighth Affirmative Defense**

Abbott adopts by reference any additional applicable defense pled by any other Defendant not otherwise pled herein.

**Forty-Ninth Affirmative Defense**

Abbott hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its Answer to assert such defense.

**JURY DEMAND**

Abbott hereby demands a trial by jury.

**WHEREFORE**, Abbott demands judgment dismissing the Complaint with prejudice, and awarding reasonable expenses and costs incurred herein, and for such further relief as the Court deems just and proper.

Respectfully submitted,

<p>Dated: September 18, 2008</p>	<p><u>/s/ Tara A. Fumerton</u> Lee Ann Russo Tara A. Fumerton JONES DAY 77 W. Wacker Dr., Suite 3500 Chicago, IL 60601-1692 Telephone: (312) 782-3939 Facsimile: (312) 782-8585</p> <p>Brent B. (Chris) Green DUNCAN, GREEN, BROWN &amp; LANGENESS, P.C. 400 Locust Street, Suite 380 Des Moines, IA 50309 Telephone: (515) 288-6440 Facsimile: (515) 288-6448</p> <p><i>Counsel for Defendant Abbott Laboratories Inc.</i></p>
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**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the **ANSWER AND AFFIRMATIVE DEFENSES OF ABBOTT LABORATORIES INC. TO THE STATE OF IOWA'S COMPLAINT** was delivered to all counsel of record by sending a copy to LexisNexis File and Serve, on September 18, 2008, for posting and notification to all parties.

September 18, 2008

/s/ Tara A. Fumerton \_\_\_\_\_  
Tara A. Fumerton